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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

| Office Action Summary | Application No. 09/910,345 | Applicant(s) SHEPARD ET AL. |
| | Examiner Carolyn L Smith | Art Unit 1631 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2003*.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-81* is/are pending in the application.

    4a) Of the above claim(s) *1-17 and 68-81* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-67* is/are rejected.

7)☒ Claim(s) *18,19,33,35,44,47,52 and 60* is/are objected to.

8)☒ Claim(s) *1-81* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
    a)☐ All b)☐ Some * c)☐ None of:
      1.☐ Certified copies of the priority documents have been received.
      2.☐ Certified copies of the priority documents have been received in Application No. _____.
      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
    * See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
    a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8 pages* .

4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Applicants' election without traverse of Group III (claims 18-67) and specie elections I (target organism which is a bacterium) and P (FAST algorithm), filed 9/16/03, is acknowledged. Claims 1-17 and 68-81 are withdrawn from consideration as being drawn to non-elected Groups.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to methods for identifying therapeutic targets for treating infectious disease, whereas in contrast the elected claim is directed to a method, system, and computer program product for identifying drug targets and enzymes.

The four Informational Disclosure Statements, filed 4/19/2002, 4/30/2002, 8/5/2002, and 10/8/02 have been considered.

Claims herein under examination are 18-67.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on page 25, lines 11-12, and pages 78-82. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Objections

Claims 18, 19, 33, 35, 44, 47, 52, and 60 are objected to because of the following minor informalities:

Claim 18, lines 2, 6, and 11 list "a.", "b.", and "c." which is an improper use of periods.

Claim 35, lines 2, 5, 8, 13 and 19 list "a.", "b.", "c.", "d.", and "e." which is an improper use of periods.

Claim 52, lines 3, 6, 11, and 15 list "a.", "b.", "c.", and "d." which is an improper use of periods.

Claim 60, lines 4, 7, and 11 list "a.", "b.", and "c." which is an improper use of periods. Please delete these periods.

Claim 18, line 8, recites the word "comprises" which should be in plural form because the word "sets" (line 7) is plural.

Claim 18, line 9, recites the phrase "that *is* different *that*" which does not make grammatical sense with the rest of section (b) of claim 18. The word "is" should be in plural form since the word "classes" (line 9) is in plural form. The phrase would also be grammatically correct if the second "that" of line 9 was changed to "than".

Claim 19, line 3, recites the word "organism" which should be in the plural form.

Claim 33, line 2, recites the word "comprises" which should be in the plural form.

Claim 44, line 2, recites the phrase "on a one" which does not make grammatical sense. Correction is suggested by deleting the word "a".

Claim 47, line 2, recites the term "comprises" which should be in the plural form.

Claim 52, line 8, recites the term "comprises" which should be in the plural form.

Claim 52, line 8, recites the phrase "one or logic" which does not make grammatical sense and

appears to be missing a word.

Claim 52 is objected to because it does not fall in the statutory class of methods and yet it

contains method steps which is inappropriate.

Appropriate corrections are requested.

Claims Rejected Under 35 U.S.C. § 101

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any
new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of
this title".

Claims 18-51 are rejected under 35 U.S.C. 101 because the claims are directed to non-

statutory subject matter. As written, the claims appear to lack any physical result performed

outside of a computer. While claims 25, 27, 40, and 42 mention outputting and displaying a list

of enzymes, the claims do not suggest that this is necessarily taking place outside of a computer.

As stated in MPEP § 2106, (IV)(2)(b), to be statutory, a claimed computer-related

process must either: (A) result in a physical transformation outside the computer for which a

practical application in the technological arts is either disclosed in the specification or would

have been known to a skilled artisan (discussed in MPEP § 2106 (IV)(2)(b)(i)), or (B) be limited

to a practical application within the technological arts (discussed in MPEP § 2106 (IV)(2)(b)(ii)).

As stated in MPEP § 2106 (IV)(2)(b)(i), the independent physical acts may be post- or

pre-computer processing activity as described below:

A process is statutory if it requires physical acts to be performed outside the computer

independent of and following the steps to be performed by a programmed computer, where those acts involve the manipulation of tangible physical objects and result in the object having a different physical attribute or structure. Diamond v. Diehr, 450 U.S. at 187, 209 USPQ at 8. Thus, if a process claim includes one or more post-computer process steps that result in a physical transformation outside the computer (beyond merely conveying the direct result of the computer operation), the claim is clearly statutory.

Another statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data (In re Gelnovatch, 595 F.2d 32, 41 n.7, 201 USPQ 136, 145 n.7 (CCPA 1979) (data-gathering step did not measure physical phenomenon); Arrhythmia, 958 F.2d at 1056, 22 USPQ2d at 1036), where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities. Schrader, 22 F.3d at 294, 30 USPQ2d at 1459 citing with approval Arrhythmia, 958 F.2d at 1058-59, 22 USPQ2d at 1037-38; Abele, 684 F.2d at 909, 214 USPQ at 688; In re Taner, 681 F.2d 787, 790, 214 USPQ 678, 681 (CCPA 1982).

As stated in MPEP § 2106 (IV)(2)(b)(ii), the computer-related process may be limited to a practical application in the technological arts as described below:

There is always some form of physical transformation within a computer because a computer acts on signals and transforms them during its operation and changes the state of its components during the execution of a process. Even though such a physical transformation occurs within a computer, such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process. What is determinative is not how the computer performs the process, but what the computer does to achieve a practical application. See Arrhythmia, 958 F.2d at 1057, 22 USPQ2d at 1036.

Claims 18-51 do not fulfill either of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims 18-51 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to be directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing.

As stated in MPEP § 2106, (IV)(B)(1), If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. Schrader, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

> – consist solely of mathematical operations without some claimed practical application (i.e., executing a "mathematical algorithm"); or
> – simply manipulate abstract ideas, e.g., a bid (Schrader, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

Claims 18-51 do not fulfill any of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims Rejected Under 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue

experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and

reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The

factors to be considered in determining whether undue experimentation is required include: (1)

the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence

or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6)

the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the

breadth of the claims. The Board also stated that although the level of the skill in molecular

biology is high, the results of experiments in genetic engineering are unpredictable. While all of

these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 18-51 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject

matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed

invention.

The method claims 18 and 35 create output in step (c) (in both claims) and step (e) (in

claim 35) wherein the target enzymes are found in bacteria but not in the one or more other

classes organisms used in the comparisons. The target enzymes of these outputs are then called

"drug targets" at the end of these steps. Calling these enzymes "drug targets" seems like an

overly bold statement to make based simply on the comparisons that take place in these methods.

In actuality, these enzymes only seem to be *putative* drug targets. It would not be until after a

large amount of additional experimentation has taken place, including synthesis of enzymes and

drugs as well as testing the enzymes against various drugs, before one of skill in the art would

consider them to be properly classified as drug targets. Therefore, claims 18 and 35 and the

dependent claims therefrom are rejected due to the lack of enablement.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the
subject matter which the applicant regards as his invention.

Claims 18-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which the applicant

regards as the invention.

Claims 24, 34, 39, 51, 52, 57, and 65 are vague and indefinite due to the unclarity of

citing an abbreviation, such as FAST, iECTA, ECTA, TCP/IP, and IPX. Correction is suggested

by amending in of the full name in parentheses. Claims 53-56 and 58-59 are also rejected due to

their dependency from claim 52.

Claims 18 (line 3-4), 35 (lines 3-4), 52 (lines 4-5) recite the phrase "first enzymes" which

is vague and indefinite. It is unclear in what reference the enzymes are considered to be "first".

For example, the enzymes could be the first enzymes produced by an organism or the first

enzymes recognized by an organism or countless other scenarios. Clarification of "first

enzymes" is requested. Claims 19-34, 36-51, and 53-59 are also rejected due to their direct or

indirect dependency from claims 18, 35, and 52.

Claim 18, line 9, recites the phrase "that is different that [sic]" which is vague and indefinite. It is unclear if this difference is referring to a difference between the expressed enzymes from the enzymes of the target organism or to a difference between the classes of organisms and the target organism. Clarification of this issue via clearer claim wording is requested. Claims 19-34 are also rejected due to their direct or indirect dependency from claim 18.

Claims 20, 24, and 39 are vague and indefinite due to the inclusion of embodiments beyond the elected invention. Correction is suggested by stating only the elected invention, such as "bacteria" and "FAST algorithm".

Claim 19, line 1, recites the phrase "the enzymes" which is rejected due to lack of clear antecedent basis. It is unclear to which group of enzymes in claim 18 that "the enzymes" is supposed to be referring. Clarification with proper antecedent basis for this phrase is requested.

Claim 21, line 1, recites the phrase "the organism" which is rejected due to the lack of clear antecedent basis. It is unclear to which "organism" in claim 18 that "the organism" is supposed to be referring. As currently written, "the organism" could be referring to the target organism (claim 18, line 4) or one of the organisms that is different than the target organism (claim 18, lines 9-10). Clarification with proper antecedent basis for this phrase is requested.

Claim 22, line 1, recites the phrase "the animal" which is rejected due to the lack of antecedent basis. Claim 22 is dependent from claim 18; however, claim 18 does not include the term "animal" in order to have proper antecedent basis. Clarification with proper antecedent basis for the phrase "the animal" is requested.

Claim 24, line 1, recites the phrase "the alignment search algorithm" which is rejected due to the lack of antecedent basis. Claim 24 is dependent from claim 18; however, claim 18 does not include the phrase "alignment search algorithm" in order to have proper antecedent basis. Clarification with proper antecedent basis for the phrase "the alignment search algorithm" is requested.

Claim 27, lines 1-4, recites the phrases "the metabolic enzymes" and "the non-metabolic enzymes" which are rejected due to the lack of clear antecedent basis. It is unclear if "the metabolic enzymes" in claim 27 (lines 2 and 3) are referring to the "metabolic enzymes" on line 2 of claim 26 or of the "metabolic target enzymes" on lines 4 and 5 of claim 26. It is also not entirely clear if "the non-metabolic enzyme" in claim 27 (lines 2-4) are referring to the "non-metabolic *target* enzymes" of claim 26 (lines 6-7). Clarification of this lack of clear antecedent bases for these phrases is requested.

Claim 28, line 1, recites the phrase "steps utilize a network" which is vague and indefinite. It is unclear how method steps can utilize anything. Instead, it seems more logical that method steps *can be performed* on a network. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 29, line 1, recites the phrase "the network" which is rejected to due the lack of antecedent basis. Claim 29 is dependent from claim 18; however, claim 18 does not include the term "network" in order to have proper antecedent basis. Clarification with proper antecedent basis for the phrase "the network" is requested.

Claim 30, lines 1-2, recites the phrase "step utilizes a user's computer" which is vague and indefinite. It is unclear how a method step can utilize anything. Instead, it seems more

logical that a method step *can be performed* on a user's computer. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 31, line 2, recites the phrase "relating to" which is vague and indefinite. It is unclear in what way the numbers are relating to the first set of enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claim 31, lines 2-3, recites the phrase "the first set of enzymes" which is rejected due to the lack of clear antecedent basis. The first enzymes mentioned as being associated with a target organism in claim 18, lines 3-4, were not previously defined as being in a set of enzymes, but rather just first enzymes. Clarification with proper antecedent basis for the phrase "the first set of enzymes" is requested.

Claim 32, line 2, recites the phrase "relating to" which is vague and indefinite. It is unclear in what way the numbers are relating to the one or more expressed enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claim 35, line 2, recites the phrase "the first data structure" which is rejected due to the lack of antecedent basis for this phrase. Amending the word "the" to "a" would nullify this rejection. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, lines 2-3, recites the phrase "the first set of information" which is rejected due to the lack of antecedent basis for this phrase. Amending the word "the" to "a" would nullify this rejection. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 7, recites the phrase "second enzymes" which is vague and indefinite. It is unclear with what reference the enzymes are considered to be second. For example, they could be the second enzymes to appear in timed response or countless other scenarios. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 7, recites the phrase "first class of organism" which is vague and indefinite. It is unclear if this type of organism is intended to be considered the same as the organism mentioned in line 4 or what constitutes an organism to be "first class." Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 9, recites the phrase "the first output" which is rejected due to the lack of antecedent basis for this phrase. Amending the word "the" to "a" would nullify this rejection. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 14, recites the phrase "relating to" which is vague and indefinite. It is unclear in what way the information is relating to the third expressed enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 14, recites the phrase "third expressed enzymes" which is vague and indefinite. It is unclear what is meant by these enzymes being third. It is unclear if these enzymes are only expressed by a third of their normal expression or countless other scenarios. Clarification of the metes and bounds of this phrase is requested via clearer claim wording. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, lines 15 and 18, recites the phrase "second class of organisms" which is vague and indefinite. It is unclear if this type of organism is the same or different from the target organism. Clarification of the metes and bounds of this phrase is requested via clearer claim wording. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 35, line 22, recites the phrase "the target enzymes" which is rejected due to the lack of clear antecedent basis for this phrase. The claim does mention enzymes as well as target organisms, but this does not provide clear antecedent basis for "the target enzymes". It is unclear if the target enzymes are supposed to be enzymes from the target organism or if the enzymes are considered targeted for some other reason. Clarification with proper antecedent basis for the phrase "the target enzymes" is requested. Claims 36-51 are also rejected due to their direct or indirect dependency from claim 35.

Claim 36, lines 1-2, recites the phrase "repeating steps (d)-(e) n times, wherein there are n data structures" which is vague and indefinite. It is unclear which data structures should be compared to which other data structures in this scenario. For example, if there are four data structures, then are there fourth expressed enzymes? Are these enzymes associated with the same second class of organism or a third class of organism? Are they different from a first class of organism and/or a second class of organism? Are the enzymes expressed at elevated levels in the new class of organisms compared to any other class of organism or the next lower class? Since countless plausible scenarios exist, clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claim 38, lines 1-2, recites the phrase "step utilizes an alignment search algorithm" which is vague and indefinite. It is unclear how a method step can utilize anything. Instead, it seems more logical that a method step *can be performed* by an alignment search algorithm. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 42, lines 2-4, recites the phrases "the metabolic enzymes" and "the non-metabolic enzymes" which are rejected due to the lack of clear antecedent bases for theses phrases. It is unclear if the "the metabolic enzymes" of claim 42 are referring to the metabolic enzymes of claim 41, line 2, or to the metabolic target enzymes of claim 41, line 4. It is also not entirely clear if "the non-metabolic enzyme" in claim 42 (lines 2-4) are referring to the "non-metabolic *target* enzymes" of claim 41 (lines 6-7). Clarification of this lack of clear antecedent bases for these phrases is requested.

Claim 43, line 1, recites the phrase "steps utilize a network" which is vague and indefinite. It is unclear how method steps can utilize anything. Instead, it seems more logical that method steps *can be performed* on a network. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 44, lines 1-2, recites the phrases "the network" and "the *n* data structures" which are rejected to due the lack of antecedent bases for these phrases. Claim 44 is dependent from claim 35; however, claim 35 does not include the terms "network" or "*n* data structures" in order to have proper antecedent basis. Clarification with proper antecedent basis for phrases "the network" and "the *n* data structures" is requested.

Claim 45, lines 1-2, recites the phrase "step utilizes a user's computer" which is vague and indefinite. It is unclear how a method step can utilize anything. Instead, it seems more

logical that a method step *can be performed* on a user's computer. Clarification of this awkward phrasing is requested via clearer claim wording.

Claim 46, line 2, recites the phrase "relating to" which is vague and indefinite. It is unclear in what way the numbers are relating to the first set of enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested.

Claims 47 and 48 (line 1 of each) recite the phrases "the n data structures in the group" and "the n data structures" which are rejected to due the lack of antecedent bases for these phrases. Claims 47 and 48 are dependent from claim 35; however, claim 35 does not include the phrases "n data structures in the group" or "n data structures" in order to have proper antecedent basis. Clarification with proper antecedent basis for the phrases "the n data structures in the group" and "the n data structures" is requested.

Claim 49, line 1, recites the phrase "the class of organism" which is rejected due to the lack of clear antecedent basis. It is unclear to which class of organism in claim 35 that "the class of organism" is supposed to be referring. As currently written, "the class of organism" could be referring to the first class of organism (claim 35, line 7) or the second class of organism (claim 35, line 18). Clarification with proper antecedent basis for this phrase is requested. Claim 50 is also rejected due to its dependency from claim 49.

Claim 52, line 9, recites the phrase "a first data structure to obtain a first set of information" which is rejected due to its unclarity regarding antecedence. It is unclear if this "a first data structure to obtain a first set of information" is the referring to the "a first data structure to obtain a first set of information" on lines 3-4 of this claim. If so, then the words "a" should be

changed to "the" to provide proper antecedent basis for this phrase. Claims 53-59 are also rejected due to their direct or indirect dependency from claim 52.

Claims 52 (lines 9 and 12), 58 (line 1), 59 (line 2) recite the phrase "relating to" which is vague and indefinite. It is unclear in what way the information is relating to the enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 53-59 are also rejected due to their direct or indirect dependency from claim 52.

Claim 52, line 10, recites the phrase "a target organism" which is rejected due to its unclarity regarding antecedence. It is unclear if this "a target organism" is the referring to the "a target organism" on line 5 of this claim. If so, then the word "a" should be changed to "the" to provide proper antecedent basis for this phrase. Claims 53-59 are also rejected due to their direct or indirect dependency from claim 52.

Claim 56, line 2, recites the phrase "the second data structure" which is rejected due to the lack of antecedent basis for this phrase. Claim 56 depends from claim 52 which does not mention a second data structure. Clarification of the proper antecedent basis for the phrase "the second data structure" is requested. Claim 57 is also rejected due to its dependency from claim 56.

Claims 60 (lines 5 and 8), 66 (line 2), and 67 (line 2) recite the phrase "relating to" which is vague and indefinite. It is unclear in what way the information is relating to the enzymes. Clarification of the metes and bounds of this phrase via clearer claim wording is requested. Claims 61-65 are also rejected due to their direct or indirect dependency from claim 60.

Claim 64, lines 2-3, recites the phrase "the second data structure" which is rejected due to the lack of antecedent basis for this phrase. Claim 64 depends from claim 60 which does not

mention a second data structure. Clarification of the proper antecedent basis for the phrase "the second data structure" is requested. Claim 65 is also rejected due to its dependency from claim 64.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 18-25, 28-30, 33, 35-36, 38-40, 43-45, and 48-50 are rejected under 35 U.S.C. 102(a) as being anticipated by Lincoln (P/N 6,553,317 B1).

Lincoln et al. disclose systems and methods for identifying genetic information and materials that may be used for further research and drug development (drug targets) (col. 1, lines 25-30 and col. 4, lines 10-14). Lincoln et al. disclose using a computer system with a relational database containing polynucleotide sequences (col. 2, lines 28-34). Lincoln et al. assessing related information by way of a user entering a query relating to one or more sequences (data structures), determining matches between the query and the information and displaying the results (col. 2, lines 38-50). In Figure 1A, Lincoln et al. disclose comparing sequences against internal databases (10) and public gene, protein, and pattern databases (16), noting matches (18), as well as unique clones (20, known as the *first output* in instant claim 1), recording the results of

matches and unique clones in tables (22) (a third data structure), and placing the results gene

expression and sequence relational databases (24). Lincoln et al. disclose investigating

biomolecular sequences from various sources, including microbial, plant, human, primate,

rodent, amphibian, and insect sequences (col. 4, lines 3-7). Therefore, Lincoln et al. illustrate if

microbial sequences were queried, then the unique clones ((20) of Figure 1A and col. 5, lines 41-

64) would include only sequences from the microbe, as stated in instant claim 19. Lincoln et al.

disclose noting variations in the relative frequency of Expressed Sequence Tags (ESTs) to detect

the differential expression of the corresponding genes (col. 1, lines 46-61). Lincoln et al. list

examples of expressed enzymes in Figure 4. Lincoln et al. disclose a protein function table

listing protein and enzyme functions (Figure 3F and col. 19, lines 15-28). Lincoln et al. disclose

categorizing master clusters (318) to classify hierarchies for enzyme function and protein

function which allows users to search all sequences in the gene expression database that are

associated with a particular protein or enzyme function (col. 18, line 66 to col. 19, line 5) which

suggests a third data structure to organize enzymes. Lincoln et al. disclose obtaining raw

sequence data involves DNA which was expressed as protein and first converted to mRNA

sequences (col. 6, lines 5-18). Lincoln et al. disclose recording bacterial sequences when

mammalian cells are being sequenced in order to study or monitor drug resistance in certain

tissue (col. 4, line 63 to col. 5, line 3). Lincoln et al. disclose using various alignment search

algorithms, such as FASTA, BLAST and Smith-Waterman (col. 10, lines 37-50; and col. 11,

lines 24-43), as stated in instant claims 23, 24, 38, and 39. Lincoln et al. disclose a network

system for storing and retrieving information (data structures) in relational databases wherein

servers and clients are connected (col. 13, lines 1-39), as stated in instant claims 28, 29, 43, and

44. Lincoln et al. disclose each client with a World Wide Web browser which provides a user interface to a server where clients can construct search requests from databases and directly access data from public domain databases (col. 13, lines 53-65 and col. 14, lines 34-41), as stated in instant claims 30 and 45. In Figure 2B, Lincoln et al. disclose the process of a user selecting sequences and adding tables to the query (168) which then go to the database (146) then to the server (136) and then back to (168) which represents a reiterative procedure as found in instant claims 35, 36, and 44. Lincoln et al. disclose the network is capable of utilizing TCP/IP protocol (col. 15, lines 24-25), as stated in instant claims 57 and 65. Lincoln et al. disclose computer program products in claims 19-34 containing computer code for various steps such as searching a first data structure via query, determining matches between query entry and other information and displaying results, as stated in instant claim 60.

Thus, Lincoln et al. anticipate the limitations in claims 18-25, 28-30, 33, 35-36, 38-40, 43-45, and 48-50.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes the subject matter of the various claims

was commonly owned at the time any inventions covered therein were made absent any evidence

to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35

U.S.C. (e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference has a common inventor with the instant application. Based upon

the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C.

102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37

CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not an invention "by another"; (2) a showing of a date of

invention for the claimed subject matter of the application which corresponds to subject matter

disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference

under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the

application and reference are currently owned by the same party and that the inventor named in

the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in

accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this

rejection might also be overcome by showing that the subject matter of the reference and the

claimed invention were, at the time the invention was made, owned by the same person or

subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and §

706.02(l)(2).

Claims 18-25, 28-40, 43-53, 55-61, and 63-67 are rejected under 35 U.S.C. 103(a) as

being obvious over Lincoln et al. (P/N 6,553,317) in view of Shepard (P/N 6,245,750) and

Lincoln et al. (P/N 6,303,297).

Lincoln et al. ('317) describe the limitations of claims 18-25, 28-30, 33, 35-36, 38-40, 43-

45, and 48-50, as discussed above (see 102(a) rejection). However, Lincoln et al. ('317) do not

describe the use of Enzyme Commission numbers, or designing Enzyme Catalyzed Therapeutic

Activation (ECTA) and iECTA compounds.

Lincoln et al. ('297) describe using a relational database that stores an expression

database with sequence data and which comprises a plurality of tables organized into categories

(col. 3, lines 38-44). Lincoln et al. ('297) describe storing Genbank location and international

EC numbers in the protein table (720) which corresponds to sequences (col. 20, lines 21-29).

Lincoln et al. describe protein function analysis consisting of numerous divisions of analysis

including enzyme hierarchy as assigned with the Enzyme Commission (EC) list and based on

level of functioning (expression) (col. 23, lines 22-35).

Shepard describes identifying potential therapeutic agents that are enzyme catalyzed

therapeutic agents (ECTA) by contacting a target with a candidate therapeutic agent or prodrug

which is selective for a target enzyme (col. 5, lines 19-34). Shepard describe in one embodiment

that a target enzyme is an endogenous, intracellular enzyme (col. 5, lines 24-26). Shepard

describe in another embodiment that a target enzyme is an expression product of an infectious

agent in the cell (col. 5, lines 32-35) which seems to fit the definition of iECTA of the instant

invention as described on page 7, lines 1-5, of the specification. Shepard describe the field of

drug discovery and designing prodrugs (col. 1, lines 15-19).

Lincoln et al. ('317) state today's researchers require advanced quantitative analyses, database comparisons, and computational algorithms to explore the relationships between sequence and phenotype via computers (col. 1, lines 38-45). Lincoln et al. ('317) state sophisticated computer database systems have been developed to make EST information manipulation easy to perform and understand (col. 1, lines 62-63). Lincoln et al. ('317) state that while relational database systems provide great power, this area of technology is still in its infancy and requires further improvements to help accelerate biological research for numerous applications (col. 2, lines 6-11). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add sequence information with biological annotations provide information in relational databases for a user provides access to this information, as stated by Lincoln et al. ('317), so that further application in research and therapeutic pharmaceutical development could occur (col. 2, lines 14-27). Therefore, a person of ordinary skill in the art would have been motivated to add Enzyme Commission numbers, as stated by Lincoln et al. ('297) in order to further classify and efficiently organize data (col. 23, lines 22-35) and then proceed with designing ECTA and iECTA compounds, as stated by Shepard, in order to accelerate biological research in the drug development area, as stated by Lincoln et al. ('317) (col. 23-25).

Thus, Lincoln et al. ('317), in view of Shepard and Lincoln et al. ('297), motivate claims 18-25, 28-40, 43-53, 55-61, and 63-67.

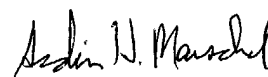## Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile

transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform with the notices published in the

Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703)

872-9306.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The

examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be

directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-

3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 1, 2003

ARDIN H. MARSCHEL
PRIMARY EXAMINER